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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,142	12/23/2005	Thomas Bar	27097U	5529
34375 7590 02/17/2010 NATH & ASSOCIATES PLLC 112 South West Street Alexandria, VA 22314				
EXAMINER DESAL, RITA J				
ART UNIT 1625		PAPER NUMBER		
MAIL DATE 02/17/2010		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/562,142

**Applicant(s)**

BAR ET AL.

**Examiner**

Rita J. Desai

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9-11, 13, 14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 14, 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-7, 9-11, 13, 14, 16-21 are in the application.

Claims 9-11, 14, 17-21 are withdrawn.

Claims under consideration are 1-7, 13, and 16.

Response to the arguments:-

Regarding the 103 rejection over WO 03/014116 Bauser et al. WO 03051877 Zhang et al, and WO 0248144 Niewohner et al. in view of GB1153670, US 4694085, Liebigs Ann. Chwm 9, 1534-1544 1981.( caplus english abstract DN 95:203671 .)

applicants argue that they have amended the claims to have R5 to be an alkyl.

Applicants have provided some data with unexpected results. That the compounds with an alkyl at the R5 position. have a better activity.

The examiner does not find this convincing first of all because the prior art does have similar antitumor activity . Modifying the compounds by substituting a H for a CH<sub>3</sub> or an alkyl is prima-facie obvious as a person skilled in the art of drug design would be motivated to make minor modifications with the expectation that the compounds would still have the same properties. The rejection is therefore maintained. KSR v Teleflex 2007.

” 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable

results;

- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 2143 for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144- §2144.09 for additional guidance regarding support for obviousness determinations.

In this case the rationale falls within the “Obvious to try with a finite number of identified, predictable solutions with a reasonable expectation of success.”

The reasoning for the rejection over Casagrande et al and Anderson et al is also the same.

The rejection of the claims under 35 USC 112 has been withdrawn as applicants have amended the claims.

Art Unit: 1625

New matter

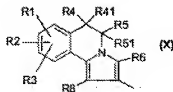
***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of R2 has been changed to include hydrogen.

This was not presented originally nor is it in the definition given in the specifications. R2 could never have been hydrogen.



in which

- R1 is halogen, nitro, 1-4C-alkyl, 1-4C-alkoxy, 1-4C-alkoxy-2-4C-alkoxy, 3-7C-cycloalkoxy or 3-7C-cycloalkylmethoxy,  
 R2 is 1-4C-alkoxy or halogen,  
 R3 is hydrogen or 1-4C-alkoxy,

On page 6 another subset is described

A subaspect (subaspect a1) of the special aspect a according to this invention worthy to be mentioned is the use of a structure-element of the formula X,

in which

- R1 is halogen, nitro, 1-4C-alkyl, 1-4C-alkoxy, 1-4C-alkoxy-2-4C-alkoxy, 3-7C-cycloalkoxy or 3-7C-cycloalkylmethoxy,  
R2 is 1-4C-alkoxy or halogen,  
R3 is hydrogen or 1-4C-alkoxy,  
R4 is hydrogen,

It should be noted that both R2 and R3 are not H.

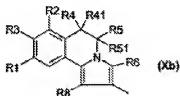
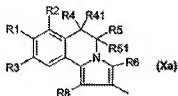
In some embodiments R2 is aH and R3 an alkyl or an alkoxy such as on page 7.

A subaspect (subaspect a2) of the special aspect A according to this invention more worthy to be mentioned is the use of a structure-element of the formula X,

in which

- R1 is halogen or 1-4C-alkoxy,  
R2 is hydrogen, halogen or 1-4C-alkoxy,  
R3 is 1-4C-alkoxy,  
R4 is hydrogen,  
R41 is hydrogen,  
R5 is hydrogen, methyl or ethyl,  
R51 is hydrogen,  
R6 is methyl, ethyl or methoxycarbonyl ethyl,  
R8 is cyano,  
as integral part of the overall structure of compounds which inhibit PDE10.

A subaspect (subaspect a3) of the special aspect A according to this invention in particular worthy to be mentioned is the use of a structure-element of the formula Xa or Xb



in which

- as a first alternative,  
R1 is chlorine or fluorine,  
R2 is hydrogen,  
R3 is methoxy or ethoxy

R1 is methoxy or ethoxy,  
R2 is hydrogen,  
R3 is methoxy or ethoxy.

There are several such subsets given in the spec. Even though some places R2 is a H, the scope that R2 and R3 both are not hydrogen. Thus between R1, R2 and R3 the ring always has to have atleast 2 substituents.

By amending claim 1 to read R2 is a H, the scope of claim 1 changes and introduces new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite “ which inhibits PDE10, comprising a structural element as an integral part of the compound's overall structure, wherein said structure-element has the formula X according to claim 1, “

Is vague and indefinite as it is unclear what else is included in the compounds. the term “comprises” is open and can include other features not in the claim.

The claims are different than those in 10/562137, 11794497, as their R7 is a phenyl instead of the methyl group in the applicants compounds.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/  
Primary Examiner, Art Unit 1625

February 5, 2010.